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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
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EXAMINER
O'HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	18

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,458	TANG ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)[·] Responsive to communication(s) filed on *18 April 2003* .

2a)[·] This action is **FINAL**. 2b)[ ] This action is non-final.

3)[ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)[·] Claim(s) *21-30 and 32-42* is/are pending in the application.

4a) Of the above claim(s) *32-34 and 38-42* is/are withdrawn from consideration.

5)[ ] Claim(s) _____ is/are allowed.

6)[·] Claim(s) *21-30 and 35-37* is/are rejected.

7)[ ] Claim(s) _____ is/are objected to.

8)[·] Claim(s) *21-30 and 32-42* ~~are~~ were subject to restriction and/or election requirement.

Application Papers

9)[ ] The specification is objected to by the Examiner.

10)[ ] The drawing(s) filed on _____ is/are: a)[ ] accepted or b)[ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)[ ] The proposed drawing correction filed on _____ is: a)[ ] approved b)[ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)[ ] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)[ ] All b)[ ] Some * c)[ ] None of:

1.[ ] Certified copies of the priority documents have been received.

2.[ ] Certified copies of the priority documents have been received in Application No. _____ .

3.[ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)[·] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) [ ] The translation of the foreign language provisional application has been received.

15)[ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

DETAILED ACTION

1. Claims 21-30 and 32-42 are pending in the instant application. Claims 21, 22, 25, 29, 30 and 36 have been amended and claim 31 has been canceled as requested by Applicant in Paper Number 17, filed April 18, 2003.

Claims 32-34 and 38-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 21-30 and 35-37 are currently under examination.

Priority

2. Applicants' amendment to the specification to recite the priority claimed in the declaration and to amend Table 2 to identify the database and sequence entry is acknowledged.

Specification

3. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 14, lines 19 and 23). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Withdrawn Objections and Rejections

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Response to Amendment

5. The declarations under 37 CFR 1.132 filed April 18, 2003 are insufficient to overcome the rejection of claims 21-31 and 35-37 based upon the lack of specific and substantial utility under 35 U.S.C. 101 35 U.S.C. 112, first paragraph as set forth in the last Office action because: they fail to provide a specific and substantial utility, as discussed below. Additionally, the two declarations are unsigned.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 21-31 and 35-37 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility (including scope of enablement and written description), for reasons of record in the previous Office Action, Paper No. 15, at pages 5-8, and below.

Applicants traverse the rejection and assert that a rejection under 35 U.S.C. § 101 is improper, as the inventions of the claims have a patentable utility as set forth in the instant specification, and/or a utility well known to one of ordinary skill in the art. Applicants assert on pages 9-10 and 23-32 of the response that the claimed invention has numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease, none of which require knowledge of how the polypeptide actually functions. Applicants assert on page 10 of the response that the similarity of the claimed polypeptide to another polypeptide of

law, and that the HCSRP-12 protein shares 86% sequence similarity with the pg120 receptor. It is further asserted that the probability that two unrelated polypeptides share more than 40% sequence homology over 70 amino acid residues is exceedingly small, and that the probability that the claimed polypeptide is related to the gp120 receptor is, accordingly, very high, and that the fact that the claimed polypeptide is a member of the C-type lectin receptor family alone demonstrates utility, and that each of the members of this class, regardless of their particular functions, are useful, and that the claimed polypeptide also has patentable utility, regardless of its actual function, and that the law has never required a patentee to prove more. Applicants cite In re Brana, and cite the enclosed references of Curtis et al., Turville et al., Bashirova et al. and Alvarez et al., which teach that the receptors identified as human L-SIGN and human DC-SIGN bind gp120, are present on dendritic cells and bind Ebola virus. Applicants submit Exhibit B, which shows a BLAST analysis of SEQ ID NO: 12 and human L-SIGN and human mDC-SIGN type I isoform. The analysis shows that with a few sequence insertions, the two receptors share 99.7% identity with SEQ ID NO: 12, which corroborates the original determination of the instant application that HCSRP-12 was correctly assigned to the class of receptors that bind to HIV envelope glycoprotein pg120. Applicants also submit Exhibit C and D, which show a C-type lectin domain in the protein of SEQ ID NO: 12. Applicants assert that is was known in the art at the time the application was filed that C-lectin receptors such as the pg120 receptor could be useful for detection of virus, inhibition of viral infection, and for development of vaccines, and that because of the relationship between the gp120 receptor and C-lectin receptor proteins as a class, persons skilled in the art at the time the application was filed would have considered

HCSRP-12 to be an important and valuable tool for use in research on cell proliferative disorders, immune system disorders, and neuronal disorders.

Applicants' arguments have been fully considered but are not deemed persuasive. It is not disputed that the protein of the instant invention is a receptor in the pg120 receptor C-lectin receptor family. However, the specification only refers to the activities or functions of all of the proteins disclosed in the specification as a group, and does not point to any activity or function that would be specific for the claimed protein of SEQ ID NO: 12. If the specification would have asserted a utility based on the high homology to other lectin-like receptors that bind viruses, that could have been a specific and substantial utility. However, the only reference to this is in Table three, sixth column, heading Homologous Sequences, which identifies Non-CD4 glycoprotein gp120 receptor GENESEQ AAR32188 as being homologous to the protein of SEQ ID NO: 12. Merely identifying that a protein is homologous to the gp120 receptor does not provide sufficient support for a specific and substantial or well-established utility.

On pages 27-29 and 301-33 Applicants argue that the precise biological role or function of an expressed polynucleotide or polypeptide is not required to demonstrate utility, that a "unique" or "particular" utility has never been required by law, and cites the PTO Utility Guidelines (66 F.R. at 1095), and that membership in a general class is insufficient to demonstrate utility only if the class contains a sufficient number of useless members such that a person of ordinary skill in the art could not impute utility by a substantial likelihood, and that as the C-type lectin receptor family is sufficiently specific to rule out any reasonable possibility that HCSRP-12 encoded by the claimed polynucleotides is useful.

Applicant's arguments have been considered but are not found persuasive. It is true that the precise biological role or function of a protein or its encoding nucleic acid are not necessary for utility, however there must be at least one specific and substantial utility attributed to the claimed invention, which has not be demonstrated, and merely identifying that a protein is homologous to the gp120 receptor does not provide sufficient support for a specific and substantial or well-established utility, as discussed above. It is not a requirement that the polypeptide have a completely unique activity in order to have a patentable utility. For example, all DNA ligases ligate the same substrate, DNA, and these proteins all have a patentable utility even though they are not completely unique in at least one activity. However, at least one specific and substantial activity must be disclosed. A specific and substantial utility for a protein that does not depend on knowledge of the activity of the protein would be use of the protein as a marker, for example, if the protein were expressed in a cancer cell but not normal cells. No such correlations or activities have been shown for the instantly claimed receptor.

On pages 25-26, Applicants assert that over the past several years, a vibrant market has developed for databases containing all expressed genes, and that the databases sold by Applicants' assignee, Incyte, include exactly the kinds of information made possible by the claimed invention, such as tissue and disease associations, and that such databases have proven to be valuable in, for example, the identification and development of drug candidates, and therefore the instant invention has commercial success and demonstrates utility.

Applicant's argument has been considered but is not found persuasive. The case law indicates that a rejection under 35 U.S.C. § 101 *for lack of operability* can be overcome by a showing of actual use or commercial success. The instant issue is whether or not the asserted

utilities meet the three-pronged test for credibility, specificity, and substantiality. Such is not necessarily addressed by a showing of commercial success or actual use. The databases sold are valuable to the scientific community because of the **potential** importance of the encoded proteins in various diseases or assays. The proteins in these cases are being used to discover what their biological significance is, and the use of a protein, or the DNA encoding it, to discover what its properties or uses are or to discover what proteins or molecules bind to it, does not constitute a specific, substantial or well-established utility, and is an invitation to experiment. If **this** specific receptor were sold because of the specific properties that the receptor possessed, this may be evidence of commercial success and utility. The selling of databases containing the instantly claimed invention is not evidence that the claimed invention has actually been used or enjoys commercial success, because the databases also contain hundreds or thousands of nucleic acids.

At p. 16 of the response, Applicants argue that, given that the claimed polynucleotide is known to be expressed, its utility as a measuring and analyzing instrument for expression levels is as indisputable as a scale's utility for measuring weight. Applicants review case law pertinent to the patentable utility of research tools. This is not found to be persuasive. Applicants analogy is misplaced. It is true that a scale has patentable utility as a research tool. However, the object being weighed on the scale does not necessarily have patentable utility. In the instant case, microarray technology has patentable utility. However, the microarray is not being claimed, but rather a polynucleotide that can be used in microarrays. The claimed polynucleotide is not disclosed as being expressed at an altered level or form in any diseased tissue as compared to the corresponding healthy tissue. Therefore, the assertion that the claimed polynucleotide has

patentable utility as a probe in, or member of, a microarray is not specific. Any orphan polynucleotide can be used in the same way.

On pages 13-23 of the response, Applicants assert that the uses of the claimed polypeptides and polynucleotides for diagnosis of conditions and disorders characterized by expression of HCSRP, for toxicology testing, and for drug discovery, are sufficient utilities under 35 U.S.C. § § 101 and 112, first paragraph, and are "well-established" uses for the claimed invention to persons of ordinary skill in the art, and that the claimed invention has specific, substantial, real-world utility by virtue of its use in toxicology testing, drug development and disease diagnosis through gene expression profiling. Applicants submit the declaration of Dr. Bedilion, which explains the many reasons why a person skilled in the art reading the Tang et al. '404 application of March 8, 1999, would have understood that application to disclose the claimed polynucleotide to be useful for a number of gene expression monitoring applications, *e.g.*, as a highly specific probe for the expression of that specific polynucletide in connection with drugs and the monitoring of such drugs. In particular, Applicants state that the Bedilion declaration describes how the claimed expressed polynucleotide can be used in gene expression monitoring systems that were well-known at the time of the invention, and how those applications are useful in developing drugs and monitoring their activity.

This has been fully considered but is not found to be persuasive for several reasons. The specification does not disclose that the claimed genes are markers for specific diseases. Absent a disclosure of altered levels or forms of a gene in diseased tissue as compared with the corresponding healthy tissue, the gene is not a disease marker or an appropriate target for drug discovery or toxicology testing.

Applicants quote from the Bedilion declaration, that states that any microarray containing SEQ ID NO: 12-encoding polynucleotides would be a more useful tool than microarrays lacking same in connection with conducting gene expression monitoring studies on proposed or actual drugs for treating cell proliferative disorders, immune system disorders, infections, and neuronal disorders for such purposes as evaluating their efficacy and toxicity. This is not found to be persuasive. Regarding the merit of the argument, any new polynucleotide can be used in a microarray, and thus this asserted utility is not specific. Also, the disclosure that HCSRP-12 is structurally related to pg120 receptor does render the asserted utility specific, since the specification does not establish that the polynucleotide and encoded protein are expressed in any diseased tissues in any way that is different from the way it is expressed in healthy forms of the same tissues. In other words, the specification does not disclose that HCSRP-12 is expressed in tissues having cell proliferative or immune system disorders, infections, and neuronal disorders at altered levels or forms. Thus, it is not a target for drug development, toxicology studies, or disease diagnosis. Significant further research would have to be conducted to identify diseases states which correlate with altered levels or forms of the claimed polynucleotides. Therefore, this asserted utility is also not substantial.

A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed polynucleotide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed polynucleotide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. However, such is not the fact pattern here. The instant

specification discloses that the claimed polypeptides are structurally related to pg120 receptor, and hypothesizes that the claimed polynucleotides and polypeptide are involved in cell proliferative immune system disorders, infections, and neuronal disorders. However, the expression of the polynucleotide in diseased tissues and corresponding healthy tissues was not evaluated. Therefore, there is no disclosure that the claimed polynucleotides are expressed at altered levels or forms in any specific, diseased tissue. Also, since the disclosure does not disclose specific diseases which should be treated with the protein, drug discovery and determining toxicity levels would have been quite meaningless.

Applicants assert on pages 15-16 that the Bedilion declaration establishes that persons skilled in the art, reading the Tang et al. '404 application at the time it was filed, would have wanted their cDNA microarrays to comprise the claimed polynucleotide, because a microarray comprising the claimed polynucleotide would provide more useful results in the kind of gene expression monitoring studies that microarrays lacking the claimed polynucleotide. This is not found to be persuasive. The specification has not linked the claimed polynucleotide with any specific disease state or disorder, as discussed above and in previous Office Actions. Adding the claimed polynucleotide to a microarray would not make the microarray any more valuable than adding any other "orphan" polynucleotide. The asserted utility is not specific to the claimed polynucleotide.

Applicants assert that the Bedilion Declaration shows that a number of pre-March 8, 1999 publications further establish the utility of cDNA microarrays in a wide range of drug development expression monitoring applications at the time the Tang et al. '404 application was filed, and that the Brown and Shalon U. S. Patent No. 5,807,522 shows that the Patent Office

recognizes the patentable utility of the cDNa technology developed in the early to mid-1990's, and that the Rockett et al. and Lahskari et al. publications describing the state of the art further confirm the claimed invention's utility.

At pages 18-23 of the response, Applicants assert that in his declaration, Mr. Furness explains the many reasons why a person skilled in the art who read the Tang et al. '404 application on March 8, 1999, would have understood that application to disclose the claimed polypeptide to be useful for a number of gene and protein expression monitoring applications, *e.g.*, in 2-D PAGE technologies, in connection with the development of drugs and the monitoring of the activity of such drugs. Applicants assert that since the early 1990's, 2-D PAGE has been used to create maps showing the differential expression of proteins in different cell types or in similar cell types in response to drugs and potential toxic agents, and that by comparing a map of cells treated with a potential drug candidate to a map of cells not treated with the candidate, for example, the potential toxicity of a drug can be assessed. Mr. Furness explains that persons skilled in the art would appreciate that a 2-D PAGE map that utilized the SEQ ID NO: 12 polypeptide sequence would be a more useful tool that a 2-D PAGE map that did not utilize this protein sequence in connection with conducting protein expression monitoring studies on proposed (or actual) drugs for treating cell proliferative disorders, immune system disorders, infections, and neuronal disorders for such purposes as evaluating their efficacy and toxicity.

On pages 19-23, Applicants assert that the use of nucleic acids coding for proteins expressed by humans as tools for toxicology testing, drug discovery, and the diagnosis of disease is now "well-established", and that toxicology testing in now standard practice in the pharmaceutical industry. Applicants also state that the more genes that are available for use in

toxicology testing, the more powerful the technique, and that the potential benefit to the public in terms of lives saved and reduced health costs, are enormous. Applicants provide evidence of the benefits of this information on pages 21-23, in which CV Therapeutics, an Incyte collaborator, was able to use Incyte gene expression technology and other information to identify the key gene associated with Tangiers disease, and state that other customers have reduced the time associated with target discovery and validation, and that over 50 percent of the drug targets in its current pipeline of another customer were derived from the Incyte database.

Applicants' arguments have been fully considered but are not deemed persuasive. There is no doubt that cDNA microarray technology is an extremely valuable technique in gene expression monitoring, toxicology testing, and drug efficacy testing. The same is true for 2-D PAGE. There is also no doubt that using such databases and technologies is very useful in discovering genes associated with diseases, or in drug discovery or toxicology testing. However, the claims are not drawn to the databases and techniques. The claims are directed to polynucleotides and polypeptides which have not been disclosed as being associated with any particular disease or condition by its being expressed at an altered level or form in diseased tissue as compared to the corresponding healthy tissue. Any such polynucleotide could be added to a microarray, and any such protein can be analyzed on a 2-D PAGE. Thus, this asserted utility is not specific. Determining the relationship between the claimed polynucleotides and any specific disease or disorder would require significant further research. Therefore, this asserted utility is also not substantial. In the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder, any information obtained from an expression profile would only serve as the basis for further

research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Therefore, for the reasons discussed in the Office Action mailed January 15, 2003, and above, the rejection based on 35 U.S.C. § 101 is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7.1 Claims 21-31 and 35-37 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for reasons of record in the previous office action, and above. Even if the specification were enabling of how to use the HCSRP-12 nucleic acid or polypeptide, enablement would not be found commensurate in scope with the claims. If one of skill in the art does not know how to use the nucleic acids or proteins the skilled artisan would clearly not know how to use nucleic acids encoding and polypeptides that are 90% identical to the amino acid sequence of SEQ ID NO: 12, or fragments of SEQ ID NO: 12.

7.2 Claims 21, 23, 26, 27, 28, 30, 35 and 37 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claim 21 to recite the functional limitation "wherein said polypeptide binds to human immunodeficiency virus glycoprotein pg120", which Applicants assert is supported by Table 2, which lists SEQ ID NO: 12 as a homolog of a known gp120 receptor.

Applicants traverse the rejection and assert the requirements necessary to fulfill the written description requirement of 35 U.S.C. § 112, first paragraph, are well established by case law, and cite *Vas-Cath Inc. v. Muhurkar,* in which the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, in which the invention is, for purposes of the "written description requirement", whatever is now claimed. Applicants also draw attention to the Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, "Written Description", in which an applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possiession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

Applicants assert that SEQ ID NOS: 12 and 25 are specifically disclosed in the application and variants are disclosed, and that the specification provides an adequate written description of the recited polynucleotide and polypeptide sequences.

Applicants' arguments have been fully considered but are not deemed persuasive. The recited structure combined with a functional limitation would usually provide adequate written description. However, in the instant case, having homology to the gp120 receptor does not mean that the instantly claimed protein binds gp120, and such was not disclosed in the specification. Therefore, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 21-30 and 35-37 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants traverse the rejection on pages 39-40 and assert that "naturally occurring" means present in or produced by nature, and that the claim language does not preclude making such sequences synthetically.

Applicants' arguments have been fully considered but are not deemed persuasive. Because all of the sequences existing in nature have not been identified, it is not known which sequences would be "naturally occurring" and which would not, so the claims are indefinite.

Conclusion

9. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER